

REMARKS

The rejection of claims 1 to 10, 35 and 37 under 35 U.S.C. 103(a) as being unpatentable over WO 01/072280 ("WO '280") in view of U.S. Patent No. 7,160,551 ("US '551") that was made in the Action of January 23, 2008, has been maintained in the present Action.

Applicants have canceled claims 1 to 10, 35 and 37. Therefore, the rejection of these claims is now moot.

The Office has also maintained the rejection of claims 34 and 40 under 35 U.S.C. 103(a) as being unpatentable over WO '280 in view of US '551 and U.S. Patent No. 6,586,354 ("US '354") that was made in the Action of January 23, 2008.

In the response filed May 23, 2008, to the first Action applicants explained that the embolization material of claim 34 is able to simultaneously (1) penetrate through a catheter and (2) maintain the form of a blood vessel without injuring the blood vessel, i.e., is capable of being deformed in response to the form of a blood vessel to allow perfect blocking. Applicants noted that the combination of WO '280, US '551 and US '354 fails to suggest an embolization material which possesses these properties.

In the present Action, the Office has taken the position that the above-noted "features" (1) and (2) of the embolization material

of claim 34 (and 40, which depends on claim 34) are not recited in the claims. Thus, the Office has not given weight to these properties.

However, the above-noted properties (1) and (2) are those of an embolization material as recited in claim 34 which contains a water insoluble poly(ethylene glycol) copolymer having both (A) "a water swelling ratio of 30% or more" and (B) forms a film having "an elastic modulus in tension of 1500 MPa or less." The results of Comparative Example 1 on pages 28 and 29 of the present application show that properties (1) and (2) are not obtained if an embolization material does not satisfy limitations (A) and (B).

WO '280 discloses a polyethylene glycol based copolymer with a high water swelling ratio, but limitation (B), that is, the specific elasticity of the polymer, and the above-noted properties (1) and (2) resulting from the combination of a high water swelling ratio with the specified elasticity of the polymer, are neither disclosed nor suggested.

Therefore, even if a polyethylene glycol based copolymer particles with a high water swelling ratio can be easily obtained by a person of ordinary skill in the art in view of WO '280, it would not have been obvious within the meaning of 35 U.S.C. § 103(a) for the art-skilled person to modify the copolymer to

provide the requisite tensile modulus of elasticity in the corresponding film.

Furthermore, the recited combination of water swelling ratio of the copolymer particles and tensile modulus of elasticity of the film are parameters result from adjustment of a complex combination of various elements, such as the ratio of hydrophobic segments and hydrophilic segments in the copolymer, the crystallinity of the hydrophobic segments, and the physicochemical interactions among the hydrophobic segments. Therefore, providing a copolymer possessing the required swelling ratio of polymer particles and tensile modulus of elasticity of the film to suitable values would have required a proper consideration of these elements by the person of ordinary skill in the art.

Factors affecting the determination of the requisite combination of water swelling ratio and tensile modulus of elasticity are explained below with reference to the properties of the copolymers prepared in the examples of the present application as illustrated in the following table.

Example	Polymer type	Proportion of PEG	Hydrophilic segments	Hydrophobic segments	Tensile modulus of elasticity	Swelling ratio	Remarks
1	PLA-PEG-PLA	29	20000	35000	230	130	
2	PLA/PCL-PEG	36	8000	20000	200	37	
3	PLGA-PEG-PLGA	48	20000	21000	200	188	
4	PLGA-PEG	42	20000	48000	380	246	
5	PEG-4xPLGA	32	20000	15500	25	251	
6	PEG-8xPLA	31	20000	8000	100	152	D/L
7	PLGA-PEG-PLGA	28	20000	36000	90	210	blend

Thus, for example, even with copolymers of the A-B-A type that are the same as the copolymers in Examples 1 and 3 of the present application, ones that use PLA with high crystallinity have a high tensile modulus of elasticity and, if noncrystalline PLGA is contained, the swelling ratio is high.

Also, even if the copolymers are composed of PEG and PLGA as in the polymers in Examples 3 and 4, the tensile modulus of elasticity is high if the hydrophobic segments are large. On the other hand, if the polymer of Example 3, which has hydrophobic segments on both sides, has a higher proportion of PEG, there is an increase in the physicochemical interactions among the hydrophobic segments, so the swelling ratio is lower.

The polymer in Example 2 is an A-B type copolymer, but since the hydrophobic segments, which have high crystallinity, are large, the tensile modulus of elasticity is high and the swelling ratio is low.

The polymer in Example 5 has short noncrystalline hydrophobic segments, so the tensile modulus of elasticity is low and the swelling ratio is high.

With a blend of polymers as in Example 7, the physicochemical interactions between the molecules are main factors, and a more complicated consideration is necessary.

US '551 and US '354, which relate to biodegradable polymers, also fail to recognize that the specified combination of limitations (A) and (B) are required to obtain an embolization material having properties (1) and (2) and fail to provide the necessary teaching, suggestion or motivation, or other reason to modify the polyethylene glycol based copolymer of WO '280 as required to obtain the embolization material of claim 34 (and the embolizing agent of claim 40 obtained by dispersing the embolization material of claim 34 in physiologic saline).

Removal of the 35 U.S.C. § 103(a) rejection of claims 34 and 40 is believed to be in order and is respectfully solicited.

The foregoing is believed to be a complete and proper response to the Office Action dated October 16, 2008, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,

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